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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,665	PALM, KAIA	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-134* is/are pending in the application.

4a) Of the above claim(s) *1-66,74,82-95 and 97-134* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *67-73,75-81 and 96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/2/02, 12/9/02*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2/25/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Election filed December 10, 2004 in response to the Office Action of September 10, 2004 as well as the supplemental response filed December 21, 2004 in response to the telephone interview of December 21, 2004 are acknowledged and have been entered. Claims 1-134 are pending in the application, claims 77-80 have been amended. Claims 1-66, 74, 82-95, 97-134 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 67-73, 75-81 and 96 are currently under prosecution.

2. It is noted that because of the complexity of the claims, the restriction requirement was drawn not only to the elected Group 37, but also to groups(A)-(I), (a)-(et) and (I-XVII). In order to be fully responsive, Applicant has properly elected a linked group from each of those Groups. It is clear however, that given the election of the entire family of Hey/HRT proteins, that claims 82 and 88 are not drawn to the elected invention because these proteins are transcription repressors and do not permit access of transcriptional components as claimed in claim 82 and that none of the Hey/HRT proteins bind to any of the proteins recited in claim 88. Rather than rejecting claims 82 and 88 as not being enabled under 35 USC 112, first paragraph or having no utility under 35 USC 101, with Mr. Curtis Herbert's authorization, those claims are being withdrawn from consideration and will only be examined as they are drawn to the remaining claims if the generic linking claim is found to be allowable.

3. Applicant's election with traverse of Group 37 claims 68-73, 75-76 and 81 is acknowledged. The traversal is on the ground(s) that since claim 67 is generic for all claims 67-110, these cannot be separate inventions except in a genus/species sense. The traversal has been considered but has not been found persuasive

because the linking claim practice is appropriate in this case and the examination of all of the groups would involve the examination of hundreds and perhaps thousands of distinct inventions and would be an undue burden on the examiner. Further, as previously set forth, should the linking claim be held to be allowable, the restriction requirement shall be withdrawn and dependent claims will be entitled to examination.

Applicant argues, in the paper submitted on September 10, 2004, that there has been no *prima facie* case for restriction and if the restriction is maintained in its present form, the opportunity to rebut the reasons for restriction is requested. The argument has been considered but has not been found persuasive because reasons were indeed set forth. It is suggested that Applicant review page 64 of the restriction requirement. Further, it is noted that Applicant has the right to petition the restriction requirement once that requirement is made final.

Applicant states that it is understood that the restriction is a de facto species restriction made under 35 CFR 1.146. Contrary to Applicant's understanding, this is not a species restriction requirement but rather a linking claim requirement with each of the combined groups linked to claim 67.

The restriction requirement is further traversed on the grounds that some of the species do not simultaneously belong in all three categories (A)-(I), (a)-(et), (I-XVII). The argument has been considered and it is clear that some of the Groups, including the elected Group do not simultaneous belong in all three categories as disclosed above. This has question has been resolved as drawn to the instantly elected invention and the claims that are not drawn to the elected group have been withdrawn from consideration pending the allowability of the generic claim.

Applicant reiterates the request that claims 67-110 be rejoined to the claims of Group 37 in the paper submitted on December 21, 2004. Upon review and reconsideration Examiner has rejoined claims 67, 77-79 and 96 to Group 37, thus claims 67-73, 75-81 and 96 will be examined. However, claims 1-66, 82-95, 97-134 will not be rejoined because different searches and issues are involved in the examination of each group and would represent an undue burden for the Examiner. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

It is noted that Applicant clarifies that the previous election of Hey/HRT is meant to include all members of the Hey/HRT family.

Specification

4. The disclosure is objected to because of the following informalities:

A. The specification on page 1 should be amended to reflect the status of the parent application serial number.

Appropriate correction is required.

B. Further, the claim of priority to a provisional application is improper, the proper claim is as follows:

"This application claims benefit to provision application **********, filed **, now abandoned."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and

shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 67-73, 75-81 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because claim 67 does not contain a positive process step which clearly relates back to the preamble. The rejection may be obviated by amending the claim, for example, to recite "A method of testing a host for a cancer condition, the method comprising testing a sample obtained from the host for an autoimmune response against a plurality of transcription modulating factors, wherein the detection of an autoimmune response against said transcription modulating factors is indicative that the host has a cancer condition."

Claims 67-73, 75-81 and 96 are indefinite in the recitation of the phrase "transcription modulating factors". The phrase includes a relative term "modulating" which renders the claims indefinite. The term modulating is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. If Applicant were able to overcome the rejection under 35 USC 112, second paragraph above, Claim 67-73, 75-81 and 96 would still be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Given the indefinite claim language, it will be assumed for examination purposes that the elected invention is drawn to a method of testing a host for a non-small cell lung cancer (NSCLC), the method comprising testing a sample obtained from the host for an autoimmune response against all of the members of the Hey/HRT protein family, wherein the detection of an autoimmune response against all of these protein family members indicates that the host has NSCLC.

The claims are drawn to a method of testing a host for a cancer condition, non-small cell lung cancer, the method comprising testing a sample obtained from the host for an autoimmune response against all of the members of the Hey/HRT protein family, whereby detection of an autoimmune response to all of the members of the Hey/HRT family indicates that the host has non-small cell lung cancer.

The specification exemplifies the detection of autoantibodies against Hey1/HRT1, Hey2/HRT2, HeyL/HRT3 in blood from patients with NSCLC (see Table 11, pages 32-34). The specification discloses on page 32 that NSCLC neoplastic disease is characterized by the presence of antibodies against HeyL/HRT3. Table 11 reveals that no NSCLC patients presented with autoantibodies to Hey1/HRT, one normal control presented with autoantibodies to Hey2/HRT2 but no Hey2/HRT2 autoantibodies were found in any of the patients tested.

One cannot extrapolate the teaching of the specification to the enablement of the claims because the specification makes clear that the method will not detect an autoimmune response against more than one of the Hey/HRT protein family members. Thus no one of ordinary skill would believe it more likely than not that the claimed method could be successfully used to test for NSCLC. Since the

specification specifically teaches that patients with NSCLC do not present with autoantibodies to either Hey1 or Hey2, one would not know how to either make or use the claimed invention. Although the specification has provided a working example that demonstrates the presence of autoantibodies to Hey3, this same example demonstrates that the invention will not function as claimed since the claims as currently constituted and elected require that detection be made with the finding of autoantibodies to all of the members of the Hey/HRT protein family.

8. Claims 67-73, 75-81 and 96 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a "cancer condition" has no clear support in the specification and the claims as originally filed. A review of the specification and claims as originally filed did not reveal the newly claimed limitation. The subject matter claimed in claims 67-73, 75-81 and 96 broadens the scope of the invention as originally disclosed in the specification. Applicant is invited to point to page and line number where support for the newly added limitation can be found.

9. Claim 80 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a "at least four antibodies against the transcription modulating factors" has no clear support in the specification and the claims as originally filed. In the response of December 20, 2004, Applicant points to p.26, lines 1-3 and to Table 11 on page 26. A review of the cited support revealed that there is no support for the newly claimed limitation. However on page 32 support is found for analyzing blood sera from individuals with NSCLC for tumor associated antibodies and Table 11 reveals support for the detection of numerous types of autoantibodies. However, neither the specification nor the claims as originally filed are drawn to the specific

limitation now recited. The subject matter claimed in claim 80 broadens the scope of the invention as originally disclosed in the specification. Applicant is invited to point to page and line number where support for the newly added limitation can be found.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 67-73, 75-78, 80-81 are rejected under 35 U.S.C. § 102(b) as being anticipated by Stockert et al (J. Exp. Med., 1998, 187:1349-1354).

The claims are drawn to a method of testing a host for a cancer condition, the method comprising testing a sample obtained from the host for an autoimmune response against a plurality of transcription modulating factors (claim 67) wherein the sample is a bodily fluid (claims 68-69), wherein the sample is used for an autoantibody against the plurality of transcription modulating factors (claim 70),wherein the assay is an ELISA (claims 71-72), wherein the cancer condition is a presence of a cancer cell in a host (claim 73), wherein the cancer cell is a lung cancer cell (claim 75),wherein the sample comprises an NK cell, a T cell, a lymphocyte, or a macrophage (claim 6), wherein the testing comprises detecting antibodies against the plurality of transcription modulators factors in the sample (claims 77-78), wherein at least four antibodies against the transcription modulating factors are detected (claim 80), wherein the host is a human (claim 81).

Given the indefinite claim language, it will be assumed for examination purposes that transcription modulating factors are any factors within the cell that either directly or indirectly affect transcription on any level. This therefore includes all moieties within a cell.

Stockert teaches a method of testing a host for a cancer condition, the method comprising testing a sample of serum obtained from the human patients with melanoma, ovarian cancer, lung cancer, breast cancer, colon cancer for an autoimmune autoantibody response against NY-ESO-1, MAGE-1, MAGE-3, SSX, Melan-A (see Table 2, page 5 of 25), wherein the assay is an ELISA (claims 71-72), wherein the cancer condition is a presence of a cancer cell in a host (see pages 2 and 3 of 25). All of the limitations of the claims are met.

12. No claims allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Susan Ungar
Primary Patent Examiner
February 25, 2005